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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,413	12/12/2003	Steven F. Bolling	ORQIS.018A	2138
20995 7590 09/11/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER KOHARSKI, CHRISTOPHER	
			ART UNIT 3763	PAPER NUMBER
			NOTIFICATION DATE 09/11/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

## Office Action Summary

Application No.

10/735,413

Applicant(s)

BOLLING ET AL.

Examiner

Christopher D. Koharski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-45 is/are pending in the application.
- 4a) Of the above claim(s) 25-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-24 and 40-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges the reply filed 5/02/2007 in which claims 1, 6, 11, 14, and 20 were amended, with new claims 40-45 added. Currently claims 1, and 3-45 are pending for examination with claims 25-39 withdrawn from a previous election restriction.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-13, 20-24 and 40-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Schweich, Jr. et al. (5,716,340). Schweich, Jr. et al. discloses a blood perfusion catheter.

Regarding claims 1, 3-13, 20-24 and 40-43, Schweich, Jr. et al. discloses a perfusion cannula (Figure 1) (31) system for directing blood through the vasculature (20) or a patient, comprising: a cannula body (30) comprising a proximal end, distal end, and at least one lumen extending therebetween (Figures 2a-2b); multiple balloons (10, 12, 14, 16) (means for creating space) located on an exterior surface of the cannula body and coupled thereto integrally, wherein one of the balloons has a tubular configuration that defines a passive lumen when deployed (24); and a means for (36) deploying the balloon within the vasculature comprising an inflation lumen, whereby

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space may be provided between a vessel wall and the cannula body when the cannula body resides within the patient to permit blood flow past the cannula body, and through the passive perfusion lumen of the balloon (Figures 1-9b). Schweich, Jr. et al. discloses further discloses several other lumens (38, 24, 34, 36) capable of delivering or withdrawing blood with the respective claimed distal to proximal lengths (Figure 1).

***Claim Rejections - 35 USC § 102***

Claims 1, 4-10, 20-23 and 40-21 rejected under 35 U.S.C. 102(b) as being anticipated by Boussignac et al. (5,000,734). Boussignac et al. discloses a probe intended to be introduced within a living body.

Regarding claims 1, 4-10, 20-23 and 40-21, Boussignac et al. discloses a perfusion cannula (Figures 1-2) (31) system for directing blood through the vasculature (20) or a patient, comprising: a cannula body (3) comprising a proximal end, distal end, and at least one lumen extending therebetween (Figure 3); a balloon (5) (means for creating space) located on an exterior surface of the cannula body and coupled thereto integrally, wherein the balloon has a tubular configuration that defines a passive lumen when deployed (8, 11); and a means for (6) deploying the balloon within the vasculature comprising an inflation lumen, whereby space may be provided between a vessel wall and the cannula body when the cannula body resides within the patient to permit blood flow past the cannula body, and through the passive perfusion lumen of the balloon (Figures 1-4).

***Claim Rejections - 35 USC § 102***

Claims 14-19 and 44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Watkins et al. (3,995,617). Watkins et al. discloses a heart assist method and catheter.

Regarding claims 14-19 and 44-45, Watkins et al. discloses a perfusion cannula system (Figures 1 and 5), comprising: a cannula (50) comprising a cannula body defining at least one lumen extending between a proximal end and a distal end, said cannula body having several apertures (50d) formed in fluid communication with said lumen; and a sleeve (55a-c) carried by the cannula on the outside and configured to be moveable (Figure 4a, 4b) relative to the aperture radially and longitudinally to selectively cover and uncover the aperture as desired when the cannula resides in a patient (Figure 2) for active perfusion, wherein the cannula also further comprises a second lumen (56a).

***Response to Arguments***

Applicant's arguments with respect to claims 1, 3-24 and 40-45 have been considered but are moot in view of the new ground(s) of rejection necessitated by Applicant's amendments.

***Suggested Allowable Subject Matter***

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner recommends additional limitations drawn to the structural/spatial aspects of the balloon (804) and apertures (836) with respect to the cannula (800) and associated lumens (see Applicant's Figure 18).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

8/30/2007



Christopher D. Koharski  
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